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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/570,737

09/28/2006

Raphael Mechoulam

0-06-058

8698

42009

7590

09/15/2009

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424 MAIN STREET

1920 LIBERTY BUILDING

BUFFALO, NY 14202

EXAMINER

HAIR, TOBY

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

09/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/570,737 | Applicant(s) MECHOULAM ET AL. | |
| | Examiner TOBY D. HAIN | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 6-16, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/17/2009, 4/6/2007, 3/7/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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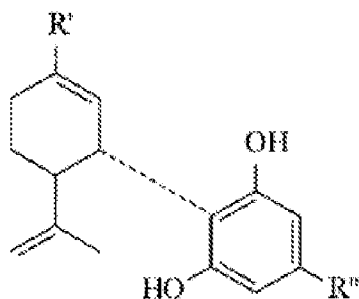
DETAILED ACTION***Claims Status***

US utility patent application 10/570,737 contains 19 pending claims. Claims 6-16, 18, and 19 are withdrawn, and claims 1-5 and 17, directed to a compound of Formula I and compositions thereof, are treated in the instant first Office action on the merits.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-5 and 17, in the reply filed on 15 July 2009 is acknowledged.

Applicant elected the species:



wherein R' is -COOH and R'' is dimethylheptyl group.

Claims 6-16, 18, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 July 2009.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

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Information Disclosure Statement

The information disclosure statements (IDS) submitted on 17 June 2009, 6 April 2007, and 7 March, 2006, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

Examiner suggests that the abstract be revised to include a chemical structure depicting the inventive concept.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites an intended use: "for use as a selective modulator of the peripheral cannabinoid system." The term "selective" has an amorphous meaning as recited. The specification suggests that the compounds are intended to be selective for peripheral cannabinoid receptors as opposed to CNS cannabinoid receptors, but the claim does not reflect how this notion is met.

Claim 17 recites an intended use "for the selective treatment of disorders associated with the peripheral cannabinoid system." The term "selectively" has an amorphous meaning as recited. The specification suggests that the compounds are intended to be selective for peripheral cannabinoid receptors as opposed to CNS cannabinoid receptors, but the claim does not reflect

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how this notion is met. Additionally, the meaning of "disorder[s] associated with the peripheral cannabinoid system" is unclear. The basis for association with the cannabinoid system is lacking. For example, it is unclear whether the claim relies on the condition being a result of a malfunction of the cannabinoid system or if the condition bears an indirect relationship with the cannabinoid system.

Claim Rejections - 35 USC § 102

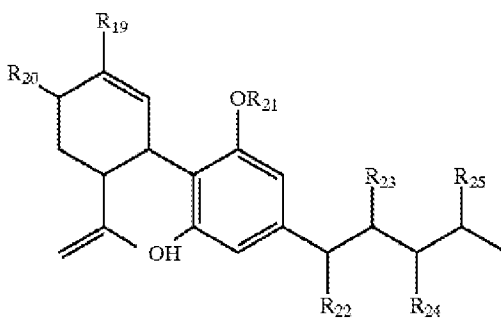
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

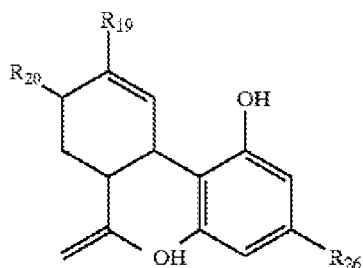
Claims 1, 2, 3, 4, 5, and 17 rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,630,507 to Hampson *et al.*

Hampson teaches at col. 5, lines 25-67, pharmaceutical compositions that include cannabinoids having the following structures



and

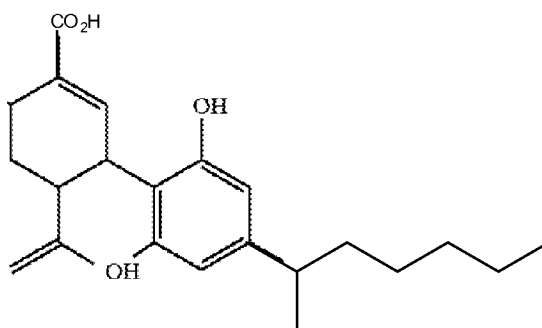
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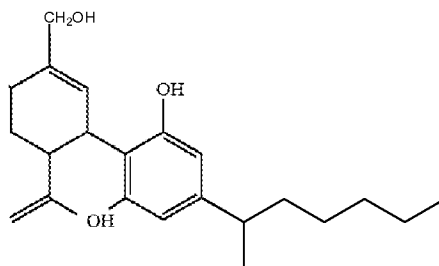
with the groups selectively defined as follows:

where R_{19} is substituted or unsubstituted alkyl, such as lower alkyl (for example methyl), lower alcohol (such as methyl alcohol) or carboxyl (such as carboxylic acid) and oxygen (as in $=O$); R_{20} is hydrogen or hydroxy; R_{21} is hydrogen, hydroxy, or methoxy; R_{22} is hydrogen or hydroxy; R_{23} is hydrogen or hydroxy; R_{24} is hydrogen or hydroxy; R_{25} is hydrogen or hydroxy; and R_{26} is substituted or unsubstituted alkyl (for example n-methyl alkyl), substituted or unsubstituted alcohol, or substituted or unsubstituted carboxy.

Note that the possible number of structure is a finitely small set, and, in particular, one skilled in the art immediately envisages a structure such as:



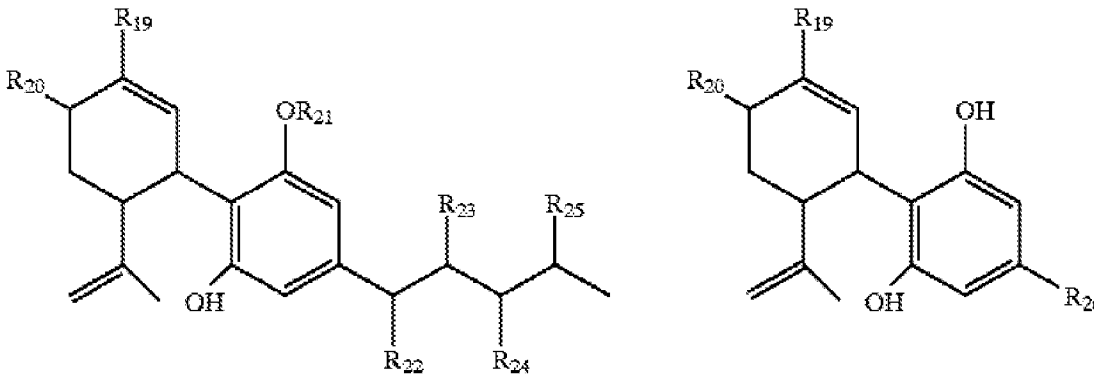
and



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Examples of structural analogs disclosed by Hampson are included in Example 11 at col.

26:

| Compound | R ₁₉ | R ₂₀ | R ₂₁ | R ₂₂ | R ₂₃ | R ₂₄ | R ₂₅ | R ₂₆ |
|--|--------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--|
|  | | | | | | | | |
| 44 CBD | CH ₃ | H | H | H | H | H | H | C ₅ H ₁₁ |
| 45 7-OH—CBD | CH ₂ OH | | | | | | | |
| 46 6α- | CH ₃ | α-OH | | | | | | |
| 47 6β- | CH ₃ | β-OH | | | | | | |
| 48 1"- | CH ₃ | | | OH | | | | |
| 49 2"- | CH ₃ | | | | OH | | | |
| 50 3"- | CH ₃ | | | | | OH | | |
| 51 4"- | CH ₃ | | | | | | OH | |
| 52 5"- | CH ₃ | | | | | | | C ₄ H ₈ CH ₂ OH |
| 53 6,7-diOH—CBD | CH ₂ OH | OH | | | | | | |
| 54 3",7-diOH—CBD | CH ₂ OH | | | | | OH | | |
| 55 4",7-diOH—CBD | CH ₂ OH | | | | | | OH | |
| 56 CBD-7-oic acid | COOH | | | | | | | |
| 57 CBD-3"-oic acid | CH ₃ | | | | | | | C ₂ H ₄ COOH |

Moreover, Hampson provides that a specific example of a lower alkyl (such as involved in R₂₆ of the structures above) is 1,1-dimehtyl heptyl. (See Hampson at col. 11, lines 50-53.)

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Hampson further teaches at col. 12, lines 50-52, that the preceding structures include both stereoisomers as well as their optically pure and active forms:

All chemical compounds include both the (+) and (-) stereoisomers, as well as either the (+) or (-) stereoisomer.

Given Hampson's teachings and known separation methods in the prior art, preparation of optically pure isomers would have been known to one skilled in the art at the time of Applicant's invention.

Additionally, Hampson teaches the additional active ingredients in the composition (at col. 19, lines 42-53):

The method includes administering the antioxidant drugs of the present invention, or a combination of the antioxidant drug and one or more other pharmaceutical agents, to the subject in a pharmaceutically compatible carrier and in an effective amount to inhibit the development or progression of oxidation associated diseases. Although the treatment can be used prophylactically in any patient in a demographic group at significant risk for such diseases, subjects can also be selected using more specific criteria, such as a definitive diagnosis of the condition.

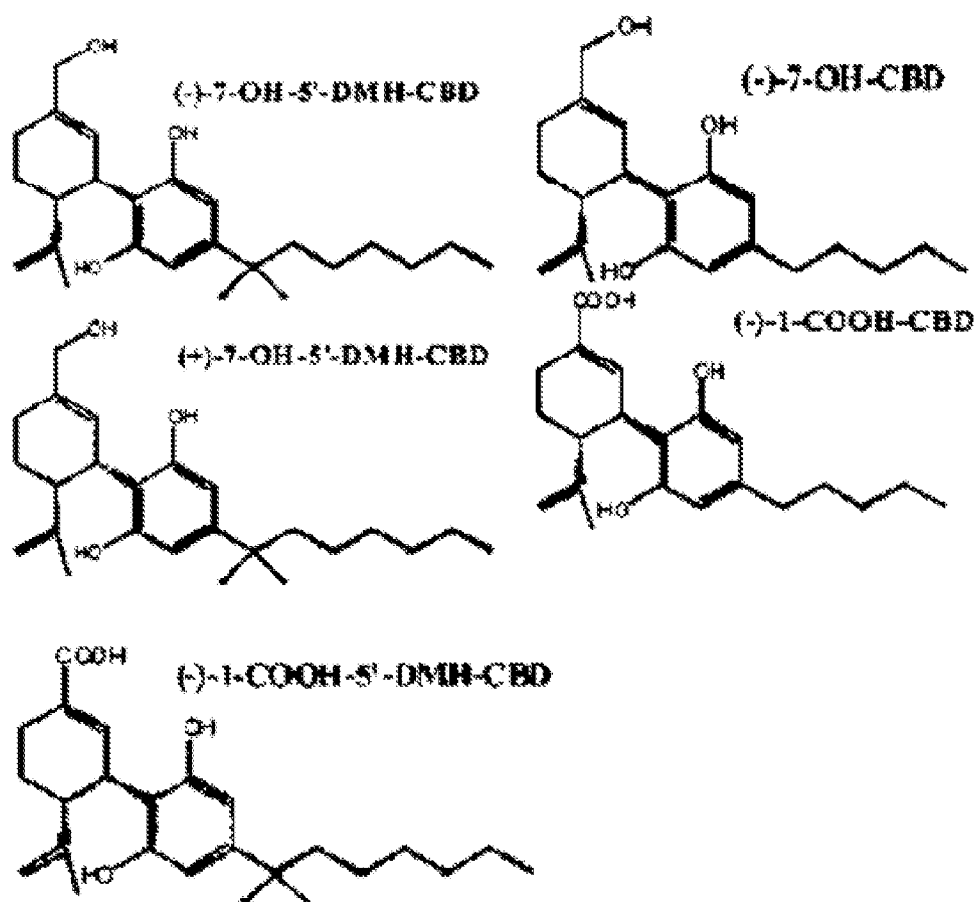
At col. 19, lines 65-68; col. 20, lines 1-10, Hampson also discloses pharmaceutical salts of the cannabinoids:

The antioxidant drugs of the invention may be administered intravenously in any conventional medium for intravenous injection such as an aqueous saline medium, or in blood plasma medium. Such medium may

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also contain conventional pharmaceutical adjunct materials such as, for example, pharmaceutically acceptable salts to adjust the osmotic pressure, lipid carriers such as cyclodextrins, proteins such as serum albumin, hydrophilic agents such as methyl cellulose, detergents, buffers, preservatives and the like. Given the low solubility of many cannabinoids, they may be suspended in sesame oil.

Applicant should also note that Bisogno (Bisogno et al., 134 Brit. J. Pharm., 845-852 (2001) at 848.) discloses the following cannabinoids:



Conclusion

No claims are patentable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TOBY D. HAIN whose telephone number is (571)270-1329. The examiner can normally be reached on Monday-Friday 9AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on (571)272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TOBY D HAIN/
Examiner, Art Unit 1621

/Daniel M Sullivan/

Supervisory Patent Examiner, Art Unit 1621